

NASA CASE NO. ARC-11258-1

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Description

Pocket ECG Electrode

1 Origin of the Invention

The invention described herein was made in the performance of work under a NASA contract and is subject to the provisions of Section 305 of the National Aeronautics and
5 Space Act of 1958, Public Law 85-568 (72 Stat. 435; 42 U.S.C. 2457).

Technical Field

The instant invention relates in general to subcutaneous electrode structures and, more particularly, to an improved
10 recording-type electrode structure particularly useful as a chronic implant for sensing electrocardiograms of active subjects.

Background Art

Heart rates and body temperatures are substantially
15 influenced, either directly or indirectly, by both the autonomic and central nervous systems, by the endocrine system, and by metabolism. Heart rate and temperatures, particularly in combinations, can therefore inherently serve to index many and various interactive responses of
20 animals to their environments. These responses include changes in activity, emotions, health, energy allocations, behavioral patterns, and biological rhythms. To develop indices based on physiological parameters, such as heart rate and body temperature, to assess animal responses it is
25 often necessary to continuously record the parameters for long periods. The changes that are then observed can be related to the context of the experiment and to the stimuli that gave rise to the responses.

Radiotelemetry has made it possible to monitor physio-
30 logical parameters in unrestrained subjects for long test

1 periods. Considerable effort has been made to develop bio-
telemetry systems small enough to be implanted in the most
commonly used laboratory animals. U.S. Patent 3,453,546,
July 1, 1969, Thomas B. Fryer, for example, reveals an
5 implantable telemeter capable of measuring temperature and
pressure.

Difficulties have been encountered in finding suitable
electrodes for providing ECG biopotentials in active unre-
strained subjects wherein the electrodes are chronically
10 implanted. When conventional ECG electrodes are moved,
artifacts are generated which tend to mask the desired bio-
potentials. If the biopotentials are very weak, it may be
impossible to distinguish them from the artifacts. It has
been found that when intracardial stimulating electrodes are
15 used for detecting biopotentials, artifact generation is
usually more pronounced than it is with standard implantable
ECG electrodes.

There is more information available on external ECG
electrodes than internal ones. In the past, designers of
20 external electrodes worried about maintaining a high load-
to-source impedance ratio to prevent amplifier loading,
signal distortion and extraneous 60-Hertz noise. Therefore,
they chose external electrodes with large distributed sur-
face areas in order to compensate for the high contact
25 impedance caused by the cornified epithelium of the skin.
Of course, as the electrode area was increased, the contact
impedance was reduced. Electrolytic pastes and jellies were
also employed to reduce the contact impedance. Internal
electrodes do not encounter a cornified epithelium and they
30 are rarely bothered by 60-Hertz stray noise. The body fluid
that engulfs the electrode when it is implanted in tissue
serves as an electrolyte. Investigators such as Geddes and
Baker have stated that subcutaneously implanted stainless
steel needle electrodes have a low enough impedance to prevent
35 amplifier loading and signal distortion (Med. & Biol. Engng.
Vol. 4, pp. 439-450, Pergamon Press, 1966).

The typical approach to the internal electrode artifact
problem has been to provide an electrode of a very small

1 surface area which could be securely anchored against the
tissue. Electrodes of this type have included small hooked
wires, needles and wire loops. Electrodes and the Measure-
ment of Bioelectric Events, L.A. Geddes, John Wiley and Sons,
5 New York 1972; Introduction to Bioelectrodes, C.D. Ferris,
Plenum Press, New York 1974; and Medical Instrumentation,
Application and Design, J.G. Webster, ed., Houghton Mifflin
Co., Boston 1978. A departure from this philosophy is found
in U.S. Patent No. 4,219,027 which discloses a smooth, stain-
10 less steel disc ECG electrode.

Body-implantable electrodes for the intracardial stimula-
tion of a heart are revealed in the following U.S. Patents:
3,664,347; 3,788,329; 3,804,098; 3,911,928 and 4,135,518.
These patents all show endocardial electrodes housed in flex-
15 ible catheters. Intracardial electrodes are used with pace-
makers and they are often designed with very small electrode
areas to minimize the current flux and the drain on the pace-
maker power supply.

Disclosure of Invention

20 The principal object of the present invention is to pro-
vide an improved subcutaneous ECG electrode useful for
chronic implant in active subjects.

Another object of the instant invention is to provide an
improved electrode with a large smooth surface area for an
25 electrode-electrolyte interface; and one in which the inter-
face is isolated from an artifact-generating environment in
a manner that does not force the desired ECG currents to
reach the interface via a constricted current path. It is
yet another object of the present invention to provide an
30 ECG electrode featuring tissue-compatible materials and whose
shape minimizes trauma to the subject. It is still another
object of the invention to provide an ECG electrode with
means for reducing flexure stress on the conductive lead
fastened to the electrode and obviating tissue pressure
35 points in the region where the lead connects to the electrode.

In order to overcome the deficiencies of the prior art
devices, and in order to achieve the foregoing objects, the

1 present invention comprises a pocket-shaped electrically con-
ductive member with a large mouth adapted to permit the
influx of body fluid so that electrical currents produced by
the ECG biopotentials may reach the inner surface of the
5 member. The member has the appearance of a squashed cylinder
that is open at one end and closed at the other end. An
electric lead capable of conveying the sensed biopotentials
to suitable monitoring apparatus is secured and electrically
connected to the closed end of the electrically conductive
10 member. The exterior surface and the mouth region of the
member are covered with an electrical insulative coating so
that the only portion of the electrode in electrical contact
with the body fluid electrolyte is situated in the lumen of
the pocket-shaped electrically conductive member. Thus, the
15 electrode/electrolyte interface is removed from tissue which
could rub there against and generate artifacts. The interior
of the pocket-shaped member provides a large smooth area for
the electrolyte/electrode interface and the mouth has a large
cross-sectional area so that the interface does not see just
20 the current flux from a small localized area where an
artifact may be present.

In one feature of the invention, cloth strips are bonded
to the electrode and electrical conductor with an elastomeric
material for reducing stress on the electrical conductor. In
25 another feature of the invention, cloth strips are bonded to
the electrode to permit the electrode to be securely sutured
to adjacent tissue.

Other features and advantages of the present invention
will become apparent upon the perusal of the following
30 specification taken in connection with the accompanying
drawings.

Brief Description of the Drawings

FIGURE 1 is a plan view of a subcutaneous ECG electrode
according to the present invention.

35 FIGURE 2 illustrates in elevational longitudinal section
the ECG electrode.

1 FIGURE 3 is a fragmentary elevational sectional view of the mouth of the ECG electrode.

FIGURES 4A and 4C depict artifacts generated by a metal disc ECG electrode.

5 FIGURES 4B and 4D show artifacts derived from a wire loop ECG electrode.

Detailed Description of the Invention

Referring now to FIGURE 1, there is shown a subcutaneous ECG electrode 11 made in accordance with the present invention for chronically deriving electrocardiograms from an active subject. A flexible electrical conductor 12, some portion of which is covered with insulation 13 to make an electrical lead, is secured to and in electrical contact with pocket-shaped electrically conductive member 14. The conductor 12 is preferably comprised of multiple strands of stainless steel wire. End 16 of the electrical conductor is adapted to be connected to monitoring equipment such as a high-impedance input amplifier and a recorder (not illustrated). At the opposite extremity from end 16 the bare conductor is doubled back on itself to form a loop 17 and the side-by-side segments of the conductor are squeezed together and tightly encircled by a metal crimp band 18. Electrode 14 has an oval cross-section and is made up of substantially parallel and coextensive walls 21, 22 and curvilinear end sections 23, 24 (see FIGURE 3). Pocket-shaped member 14 may be constructed from a flattened tube with a substantially uniform wall thickness. The common practice of using solder and solder flux to make connections to electric leads has been found to cause problems in implants. Tissue toxicity responses and deterioration of the connection due to battery potentials that arise from the metal discontinuities and flux chemistry are likely to result when soldered joints are implanted. Spot welding and crimping have been found to be better ways of making connections. After member 14 reaches the stage of fabrication where it looks like a squashed metal cylinder, electrical

1 conductor loop 17 is inserted into end 19 of member 14, end
19 is crimped closed and loop 17 is spot welded to member 14.
For example, the loop may be spot welded to member 14 at
points 20. End 26 of member 14 is left open and forms a
5 mouth or entrance to the pocket so that when the electrode
is implanted body fluid may flow into the lumen or chamber 27
(see FIGURE 2) and wet the interior surfaces. Thus, the body
fluid which is an electrolyte, permits electric currents gen-
erated by the subject's heart to reach the inner metal walls
10 of pocket-shaped member 14.

A material which is tolerated reasonably well by tissue
and which is suitable for member 14 is stainless steel.
Silver is less durable and somewhat toxic; however, it may
be used as an alternative. Cloth straps 25 are glued to the
15 outer surfaces of electrode walls 21 and 22 near electrode
mouth 26. A second set of cloth straps 28 are glued to the
outer surfaces of walls 21 and 22 in the proximity of con-
ductor loop 17. A polyester cloth such as coarse woven
Dacron® has been found to be compatible with tissue. Cloth
20 straps 29 are also placed over and normal to straps 28.
These straps are adhered to member 14, straps 28 and conduc-
tor 12. Straps 29 provide stress relief for conductor 12
when forces are exerted on it in the direction away from
member 14. Straps 29 also reduce the likelihood of the
25 electrical conductor therebetween kinking and producing a
tissue pressure point. Once the pocket electrode is in place
in a subject, it may be secured to the subject's tissue by
sutures 31. The exterior surface of member 14 as well as
the mouth region, plus the cloth straps and a portion of the
30 electrical conductor adjacent the electrode are covered with
a tissue-compatible elastomeric electrical insulation 32 of
very high impedance. The preferred insulation is silicone
rubber and this material may also be used to glue the cloth
straps to electrode 14. Further, silicone rubber may be used
35 as insulation 13 for electrical conductor 12.

When the pocket electrode is implanted in a subject,
body fluids touch the exterior surfaces and fill lumen 27;

1 however, the body fluids are only permitted electrical con-
tact with the interior walls of member 14. Some of the
advantages of the pocket electrode are believed to derive
from the creation of an electrode/electrolyte interface that
5 is removed from tissue/electrode disturbances. The portions
of the electrode that can be touched by tissue are elec-
trically insulated. Lumen 27 can be reached by electrolytes
in the form of body fluids, but not by tissue. The mouth of
the pocket electrode is relatively large and the exposed
10 electrode surface on the interior of the pocket electrode is
smooth and much larger than that of a typical ECG electrode
such as a lead loop electrode. Accordingly, it is believed
that the path of current flux into the lumen is not unduely
constricted and thus not easily perturbed, and that any
15 extraneous localized region of cellular or mechanical
activity fails to rise to a noticeable level as would be the
case with a small conventional ECG electrode.

The electrode is easy to clean and to keep clean during
surgery. It is not prone to tissue imbedding and thus the
20 electrical performance tends to remain constant with time.
The electrode has a thin silhouette with no objectionable
protrusions. The electrical lead tends to remain flat where
it connects to the electrode. Accordingly, the electrode may
be subcutaneously accommodated with relative comfort and no
25 fear of unpleasant pressure points or rejection. When
implanted, the electrodes should be placed to the side of
the skin incision to facilitate revascularization of the skin.
The axis of incision when in the anterior-posterior plane
minimally disrupts the vascular bed. Generally, the larger
30 the size of the electrode, the more the vascularization of
the overlying skin is undesirably reduced. In one experiment
involving a labrador dog as a test subject, an electrode made
in accordance with the subject invention was utilized and it
had a wall 21 that was 2.5 cm long, 1 cm wide, and .010 inches
35 thick. The experiment had a duration of three months and
when the electrode was examined after the experiment it was
noted that no tissue had entered lumen 27.

1 In vitro tests with two prior art ECG electrodes as well
as the present invention were conducted to simulate the
2 in vivo environment. Tests were performed on lead loop elec-
trodes, disc electrodes of the type described in U.S. Patent
5 No. 4,219,027, and electrodes made in accordance with the
subject invention. A pair of each type of ECG electrodes
was immersed in an 0.9% saline bath and one electrode was
rubbed between two fingers to simulate the electrode/tissue
motion encountered in an active subject. The electrodes
10 were coupled to monitoring apparatus with a 10-megohm input
impedance. In one test, the monitoring apparatus included a
10-100 Hz bandpass filter whereas in another test the filter
was removed and the apparatus had d-c response. FIGURES 4A
and 4C depict the artifacts generated when the disc electrode
15 was rubbed, and FIGURES 4B and 4D illustrate the artifacts
that were produced when the lead loop was rubbed. The band-
pass filter was employed when the artifacts of FIGURES 4C
and 4D were generated. It is quite evident from the poten-
tial plots that the lead loop electrode generates more
20 artifacts, by at least an order of magnitude, than the disc
electrode. On the other hand, when a pocket electrode made
in accordance with the present invention was rubbed between
fingers in the saline solution, neither baseline shifts
(d-c voltages) nor oscillations (a-c voltages) were observed.
25 That is, no artifacts were generated when the electrode
perturbed.

Those skilled in the art will appreciate that the
specific structures and methods of operation described herein
may be altered without departing from the spirit and scope
30 of the invention.

Pocket ECG Electrode

Abstract

- 1 A low-noise electrode suited for sensing electrocardio-grams when chronically and subcutaneously implanted in a free-ranging subject. The electrode comprises a pocket-shaped electrically conductive member with a single entrance
5 adapted to receive body fluids. The exterior of the member and the entrance region is coated with electrical insulation so that the only electrolyte/electrode interface is within the member remote from artifact-generating tissue. Cloth
10 straps are bonded to the member to permit the electrode to be sutured to tissue and to provide electrical lead flexure relief.